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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/773,815	02/06/2004	Lukas Eisermann	31132.40	8264

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EXAMINER	
PELLEGRINO, BRIAN E	
ART UNIT	**PAPER NUMBER**
3738	

MAIL DATE	DELIVERY MODE
01/30/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)
	10/773,815	EISERMANN ET AL.
	Examiner	Art Unit
	Brian E. Pellegrino	3738

CT

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 November 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *12-21 and 31-39* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *12-21 and 31-39* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *06 February 2004* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/9/07 has been entered.

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the "implant" inserted **between** the first and second vertebrae in *combination* with the first and second insertion members inserted into the sidewall that are connected by an elongate member or a connecting member that spans the distance between the vertebrae must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure

is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 14-16 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the preparation of the vertebrae by possibly forming bores in the sidewall that receives the insertion members or screws, does not reasonably provide enablement for laterally forming slots in the first and second vertebrae. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. For example, how is it possible to form lateral slots if the sidewalls of the vertebrae receive the screws for the attachment of the elongate

member, i.e. rod of which is attached to the lateral side spanning the vertebrae? The specification gives no inclination that the slots which are for an intervertebral implant are used in the procedure with the connecting rod apparatus.

Claims 31-39 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The disclosure does not describe the method of correcting spondylolisthesis as including the use of lateral screws and an elongate member or rod *in combination* with insertion of an implant **between** the vertebrae. How is this possible? If the lateral slots are formed for the implant, there is no safe area in the lateral sidewall then to receive the bone screws for the elongate rod or vise versa. The claims recite both apparatus (implant and correction rod system) are inserted or used laterally, thus it is not possible to perform this with both sets of apparatus used laterally as claimed in claim 36. Regarding claim 37, the disclosure describes the insertion of the apparatus described above, but fails to describe removal of the apparatus.

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 12,13,17,21,31-35,38 are rejected under 35 U.S.C. 102(b) as being anticipated by Laurain (5108395). Laurain discloses a method for correcting a spinal condition having incorrect curvature by removing an intervertebral disc, col. 1, lines 25-30, col. 6, lines 49-52. The surgeon then inserts laterally into the sidewall of the vertebrae, clamps and bone screws, (Figs. 1,9) and then a connecting member **6** is joined to engage the clamps to span between the vertebrae. Laurain discloses that a rotating force is applied to the connecting member to rotate the vertebrae relative to one another, col. 3, lines 4-16, col. 7, lines 18-21,47-52. With respect to claim 13, the examiner is interpreting the claimed elements "prosthetic joint" in this way: an object between the vertebrae in the "joint" space. Claims in a pending application should be given their broadest reasonable interpretation. *In re Pearson*, 181 USPQ 641 (CCPA 1974). See also *In re Morris*, Fed. Cir. 1997 127 F3d 1048, 1054,1055. Thus, since Laurain illustrates (Fig. 8,9) a prosthetic graft **G** in the joint space, it can be considered a "prosthetic joint". Regarding claim 21, it is inherent that the surgeon uses a wrench to rotate the screws in there hex or head sections. A surgeon cannot use his hands to do this. With respect to claim 33, it is known in the art that grafts promote fusion. Regarding claim 34, it is inherent that the graft will permit some articulation or motion (which can be compression) between the vertebrae. Since placement of the elongate member **6** is on the lateral side of the vertebrae, it can be considered a lateral approach.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim 36 is rejected under 35 U.S.C. 103(a) as being unpatentable over Laurain '395. Laurain is explained supra. However, Laurain fails to disclose the implant is inserted laterally. It would have been obvious to one of ordinary skill in the art to insert the implant while performing the surgery in the patient to place the implant laterally into the patient before placing the elongate member onto the screws since this would not require any more incisions in the patient since the lateral side has been exposed. It is common sense that a surgeon would minimize the incisions a patient would require such that the healing is kept to a minimum.

Claims 18,19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Laurain '395 in view of Wagner et al. (6030389). Laurain is explained supra. However, Laurain fails to disclose the type of screws used in the surgical procedures. Wagner et al. teach that there are two types of screws used in spinal stabilization procedures, bi-cortical and uni-cortical and enable the surgeon to decide which to use based on the type of device the screws are used with, col. 1, lines 31-44. It would have been obvious to one of ordinary skill in the art to utilize either bi-cortical or uni-cortical as taught by Wagner et al. in the method of spinal repair with the spinal implant of Laurain such that the implantable screws and connectors remain in place and provide the proper alignment for the patient.

Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Laurain '395 in view of Bryan (5306275). Laurain is explained supra. However, Laurain fails to disclose the connecting member is a rod. Bryan teaches (Fig. 12 that connecting members spanning between vertebrae can be rods **12**. It would have been obvious to

one of ordinary skill in the art to modify the connecting member to be a rod as taught by Bryan with the system and method of Laurain such that it provides an easier elongate member to work with. Modifying couplings and connecting members is well within the skill of an expert in engineering and manufacturing spinal devices.

Claim 37 is rejected under 35 U.S.C. 103(a) as being unpatentable over Laurain '395 in view of Jacobson et al. (5382248) and Conchy et al. (6749612). Laurain is explained supra. However, Laurain fails to disclose disengaging the elongated member from the insertion members and removing it along with the insertion members from the sidewall of the vertebrae. Conchy et al. teach (Fig. 8) that rods **2,3** spanning between vertebrae can be removed, col. 6, lines 28-30. Jacobson et al. teach that bone screws can become loose and broken to require removal, col. 6, lines 16-26, col. 12, lines 11,12,35-45. It would have been obvious to one of ordinary skill in the art to remove an incorrect elongate member as taught by Conchy et al. and broken screws as taught by Jacobson et al. from the vertebrae inserted by the method of Laurain such that problems with the correction apparatus can be corrected if necessary.

Claims 12,13,17,20,21,31-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Thomas et al. (6964665) in view of Laurain '395. Thomas et al. disclose (Fig. 7c) a spondylolisthesis correction system including bone screws **12** laterally inserted into first and second vertebrae and a connecting member or rod **50** is spanned between the vertebrae. Thomas shows the spondylolisthesis condition and discloses the system is used to correct this condition, col. 6, lines 45-51. However, Thomas et al. fail to disclose that the spinal disc would need to be removed or to place

an implant between the vertebrae. Laurain is explained above. It would have been obvious to one of ordinary skill in the art to remove disc material if necessary or degenerative as taught by Laurain when performing the procedure of Thomas et al. and inserting bone screws and a connecting member laterally such that no further damage or painful conditions continue and the degenerative area is stabilized. With respect to claim 21, it would have been an obvious expedient to use a rotatable wrench to rotate the connecting member as such only involves routine skill in the art and would give the surgeon good torque to move the rod.

Claims 14-16,39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Thomas et al. '665 in view of Laurain '395 as applied to claim 13 and 31 above, and further in view of Marnay (5314477). Thomas et al. as modified by Laurain is explained supra. Laurain does disclose other bone substitutes can be placed between the vertebrae or an implant so long as it maintains the vertebral spacing, col. 7, line 1-6. However, Thomas in view of Laurain fail to disclose the laterally forming slots in the vertebrae for laterally extending keels on a bone substitute implant inserted between the vertebrae. Marnay teaches to form lateral slots in the vertebrae, col. 3, lines 7-13,17,18,48-50, col. 7, lines 37,52,53. Marnay also shows (Fig. 2) laterally-extending keels to fit in the slots prepared in the vertebrae. Marnay also illustrates (Fig. 1) the bone substitute implant maintains space between the vertebrae. It would have been obvious to one of ordinary skill in the art to use the teaching of Marnay to prepare slots for laterally–extending keels of a bone substitute implant and modify the device of Laurain incorporated into the method of Thomas et al. such that the vertebral engaging

members that are part of the joint replacement device has a larger attachment surface area by using keels which would better stabilize the implant between the vertebrae and not be displaced.

Response to Arguments

Applicant's arguments with respect to claim 12 have been considered but are moot in view of the new ground(s) of rejection. Applicant's arguments filed 11/9/07 have been fully considered but they are not persuasive. Applicant alleges that Thomas '665 does not disclose laterally inserting the insertion members into the sidewall of the vertebrae. First the Examiner would like to reiterate what was in the prior action and as mentioned above, Fig. 7c clearly illustrates the vertebrae with sidewalls having the insertion members inserted therein. Second even if the screws are inserted into the pedicle part of the vertebrae as Applicant argues, this is a sidewall of the vertebrae. Thus, Thomas does disclose inserting into the sidewall insertion members as claimed. Applicant additionally argues that Thomas does not teach rotation of the rods to rotate the vertebrae. As mentioned above, Thomas clearly teaches rotation and other methods to correct spinal deformities. In response to Applicant's arguments, that Thomas only discloses a "substantial" lateral approach to correct spondylolisthesis and the Applicant is claiming a "substantial" lateral approach, is incorrect. There is no mention of where Thomas specifically teaches posterior insertion. Second, it is also contradictory in the approach of the procedure being claimed and disputed to be used by Thomas since Applicant claims a "substantial" lateral approach and that Thomas is "substantial"

posterior. These locations are adjacent and since substantial is used to describe both there must be some overlap. Therefore, Thomas must disclose the same approach.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian E. Pellegrino whose telephone number is 571-272-4756. The examiner can normally be reached on M-Fr (8:30am-5pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

BRIAN E. PELLEGRINO
PRIMARY EXAMINER
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